

## AGENDA Region 7 Meeting Chicago, IL May 21, 2010

\*All times except the start time are approximate. Actual times will be determined by the amount of discussion. \*\*A working lunch will be served

#### 9:00 Registration and Continental Breakfast

#### 9:30 Welcome/Opening Remarks

Jack Lake, MD Region 7 Councillor

- Fall regional meeting summary
- March 2010 Live Meeting Public Comment results
- November 2009 OPTN/UNOS Board meeting summary
- 2010 Committee Nominations
- Fall meeting date and venue
- Collaborative Activities

#### 9:45 UNOS Update

Walter Graham Executive Director, UNOS

#### 10:30 OPTN/UNOS Public Comment Proposals and Committee Reports

Moderator: Jack Lake, MD

Region 7 Councillor

#### Liver and Intestine Committee Proposals and Report

Anthony D'Alessandro, MD

# 1. Proposed Ohio Alternative Local Unit (ALU) Liver and Intestinal Organ Transplantation Committee (Liver and Intestinal Organ Transplantation Committee)

Three Donation Service Areas (LifeBanc, Life Connection of Ohio and LifeCenter Organ Donor Network) are requesting a single, combined new Alternative Local Unit in the State of Ohio. There will be a single waiting list within the ALU for liver allocation. This will allow for better and more efficient allocation of organs to those on the waiting list with the most urgent need over a larger geographic area.

# 2. Proposed OneLegacy Variance for Segmental Liver Transplantation (Liver and Intestinal Organ Transplantation Committee)

OneLegacy and the five liver transplant programs in its donation service area (DSA) are proposing a variance to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). This variance would permit the institution performing the right and left lobe splits to transplant one lobe into the institution's index patient and the other lobe into any other medically suitable patient listed at the institution. The variance is intended to increase the donor pool by providing an incentive to the institution receiving a liver offer to split a good-quality organ and transplant it in two recipients (an adult and a child) rather than transplanting the entire organ in one recipient

# 3. Proposed Region 2 Variance for Segmental Liver Transplantation (Liver and Intestinal Organ Transplantation Committee)

Region 2 is proposing a variance to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). This variance would allow a transplant center in Region 2 that accepts a liver for a candidate suitable for a segmental transplantation to transplant the right lobe into the institution's index patient and the left segment into any other medically suitable patient listed at that institution or an affiliated pediatric institution. This variance is intended to increase the number of transplants, allowing a single liver to be divided into two segments for transplantation, and thus removing two patients from the waiting list instead of one.

#### Pancreas Transplantation Committee Proposal and Report Brian Flanagan, PhD

4. Proposal to Develop an Efficient, Uniform National Pancreas Allocation System: Affected Policies: Policy 3.8 (Pancreas Allocation Policy), Policy 3.5 (Kidney Allocation Policy), Policy 3.2 (Waiting List), Policy 3.3 (Acceptance Criteria), Policy 3.4 (Organ Procurement, Distribution And Alternative Systems For Organ Distribution Or Allocation), and Policy 3.9 (Allocation Systems for Organs not Specifically Addressed) (Pancreas Transplantation Committee)

The purpose of this proposal is to improve the national pancreas allocation system. This improvement is consistent with the OPTN long-range strategic goals and priorities:

- to increase geographic equity in access and waiting time to deceased donor organs for transplantation;
- to maximize capacity of deceased donor organ transplantation;
- to achieve operational efficiency and cost-effectiveness of implementing and maintaining the organ allocation system.

Specific objectives of the proposed allocation system for pancreas transplantation:

- reduce geographic inequities of pancreas utilization, access to transplantation, and transplant waiting time:
- maximize capacity by improving the opportunity for pancreas candidates to receive a transplant;
- enhance efficiency and cost-effectiveness, and minimize complexity of implementing and maintaining the operational requirements of a new pancreas allocation system; and
- optimize pancreas transplant access without adversely affecting kidney transplantation. Specifically, the Committee evaluated the transplant volume for adult and pediatric kidney recipients as well as ethnicity, age, and gender of recipients.

#### Methodology to achieve these objectives:

- combine pancreas-alone (PA) and simultaneous pancreas-kidney (SPK) candidates onto a single match run list;
- allow local candidates who are allocated a pancreas from the combined list but who also require a kidney transplant, to receive a kidney independently of the kidney-alone match run if they meet specific qualifying criteria;
- institute objective medical qualifying criteria relating to renal dysfunction and diabetes for SPK candidates to accrue waiting time;
- allocate deceased donor pancreata separately from the current kidney allocation system so that
  pancreas candidates are allocated organs that precede kidney paybacks and pediatric and adult
  kidney-alone (KI) recipients
- monitor allocation of standard criteria deceased donor kidneys for pediatric and adult KI recipients and SPK recipients with respect to donor ages ≤35 and >35 years, as well as ethnicity, age and gender.

#### Ad Hoc Disease Transmission Advisory Committee Proposal

Mike Ison, MD

5. Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events: Affected/Proposed Policies: Policies 2.0 (Minimum Procurement Standards for An Organ Procurement Organization), 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Diseases or Medical Conditions, Including Malignancies, of Donor Origin), and 5.5 (Documentation Accompanying the Organ or Vessel) (Ad Hoc Disease Transmission Advisory Committee)

The proposed modifications are meant to clarify and/or improve current OPO and transplant center requirements for screening for, communicating and reporting all potential or confirmed donor-related disease and malignancy transmission events. These changes are expected to:

- Help improve patient safety and recipient outcomes by making policy consistent with current clinical testing practices in the organ recovery transplant communities and creating a Patient Safety Contact;
- Place all content related to donor evaluation and screening into one policy section;
- Further define and standardize the elements of informed consent and the communication of clinically significant information regarding potential disease transmission events; and
- Provide a clear, plain language policy format that will be easier for members and other readers to understand and follow.

### Histocompatibility Committee Proposals and Report

David Maurer, PhD

6. Proposal to Update HLA Equivalences Tables Affected/Proposed Policy: UNOS Policy 3 Appendix A (Histocompatibility Committee)

The purpose of this proposal is to update the tables in Appendix 3A to reflect changes in HLA typing practice and to improve the utility of the unacceptable antigens. Appendix 3A includes 2 tables, one listing HLA antigen designations that should be considered equivalent for purposes of matching kidney candidates and donors for the HLA-A,-B, and –DR antigens (HLA Antigen Values and Split Equivalences) and a second for determining which donor HLA antigens are unacceptable based on the unacceptable HLA-antigens listed for a sensitized candidate (HLA A, B, C, DR, and DQ Unacceptable Antigen Equivalences).

7. Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-pancreas, Pancreas, and Pancreas Islet Offers Affected/Proposed Policy: UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing D HLA Typing D1.000 Essential Information for Kidney Offers 3.8.2.2 Essential Information for Pancreas Offers (Histocompatibility Committee)

This proposal would require that OPOs and their associated laboratories perform HLA typing of deceased donors by DNA methods and identify the HLA-A, -B, -Cw, -DR and -DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet offers.

# Living Donor Committee Proposals and Report

Eugenia Steffens, RN

8. Proposal for the Placement of Non-Directed Living Donor Kidneys: Affected Policy: 12.5.6 (Recipient Selection for Organs from Nondirected Living Donor Organs) (Living Donor Committee)

This proposal would establish procedures for the placement of non-directed living donor kidneys. Under the proposal, transplant centers would select the recipient of non-directed living donor kidneys based on a list generated by the OPTN computer system used to identify potential recipients for transplant. This list is referred to as a match run. The goal of this proposal is to foster equitable organ placement and safety of the recipient.

- 9. Proposal to Require Reporting of Non-utilized and Redirected Living Donor Organs New Proposed Policy: Submission of Non-utilized Living Donor Organs (Policy 12.8.5) and Submission of Redirected Living Donor Organs (Policy 12.8.6) (Living Donor Committee)

  These proposals require that the organ recovery center report all instances of:
  - living donor organs recovered but not utilized for transplant
  - living donor organs recovered but then redirected and transplanted into a recipient other than the intended recipient.

These events would be reported through the UNet<sup>SM</sup> Patient Safety System. If a living donor organ is transplanted into a recipient other than the intended recipient, all required donor and recipient information must still be submitted through Teidi.

### Organ Procurement Organization Committee Proposal and Report

Meg Rogers

10. Proposal to Require a Use of a Standardized, Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO when they Repackage an Organ Affected/Proposed Policy: Policy 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials (Organ Procurement Organization (OPO) Committee)

Current OPTN policy only requires that the external label distributed by the OPTN contractor be used for transporting organs and vessels. This proposed policy change would require OPOs and transplant centers to also use standardized, internal labels that are distributed by the OPTN contractor for organ and vessel transport and for vessel storage. This change will make both internal and external labeling consistent throughout the U.S. The proposal also:

- requires transplant centers to notify the recovering OPO when they repackage an organ;
- makes the language consistent by changing the term "provided" by the OPTN contractor to the term "distributed" by the OPTN contractor;
- moves Policy 2.5.6.1 which lists the required documentation that accompanies an organ or vessel to policy 5.5.1.
- clarifies labeling requirements for vessel storage

### Kidney Committee Report

Mikel Prieto, MD

In its continued work to develop a new, national kidney allocation system, the Kidney Transplantation Committee will circulate a concept document during the spring of this year. The main concepts presented include an allocation system based on candidate/donor age matching and estimated survival. These concepts were developed based on feedback and recommendations from the transplant community and general public over the course of several years. The Committee will present these concepts during the spring 2010 regional meetings with the purpose of soliciting additional feedback to be incorporated into a formal public comment proposal for circulation later this year

#### **Ethics Committee Report**

Finance Committee Report
Membership and Professional Standards Committee Report
Operations and Safety Committee Report
Minority Affairs Committee Report
Organ Availability Committee Report
Pediatric Committee Report
Patient Affairs Committee Report

Tammy Kispert Yolanda Becker, MD Julie Heimbach, MD Beth Plahn, RN

Bhargav Mistry, MD

Linette Boysen Meyer, RN Nissa Erickson, MD Alison Walsh Thoracic Committee Report
Transplant Administrators Committee Report
Transplant Coordinators Committee Report

Robert Love, MD David Hefner Karen Kasinger, RN